



General

Guideline Title

Role of assisted hatching in in vitro fertilization: a guideline.

Bibliographic Source(s)

Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology. Role of assisted hatching in in vitro fertilization: a guideline. Fertil Steril. 2014 Aug;102(2):348-51. [19 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report [Clinical Practice Guidelines We Can Trust](#).

■■■■■= Poor ■■■■= Fair ■■■■= Good ■■■■= Very Good ■■■■= Excellent

Assessment	Standard of Trustworthiness
NO	Disclosure of Guideline Funding Source
■■■■■	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
UNKNOWN	Methodologist Involvement

■ ■ ■ ■ ■	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
■ ■ ■ ■ ■	Search Strategy
■ ■ ■ ■ ■	Study Selection
■ ■ ■ ■ ■	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
■ ■ ■ ■ ■	Grading the Quality or Strength of Evidence
■ ■ ■ ■ ■	Benefits and Harms of Recommendations
■ ■ ■ ■ ■	Evidence Summary Supporting Recommendations
■ ■ ■ ■ ■	Rating the Strength of Recommendations
■ ■ ■ ■ ■	Specific and Unambiguous Articulation of Recommendations
■ ■ ■ ■ ■	External Review
■ ■ ■ ■ ■	Updating

Recommendations

Major Recommendations

Definitions for the level of the evidence (Level I-III) and strength of the recommendations (Grade A-C) are given at the end of the "Major Recommendations" field.

Summary

Despite its widespread and longtime use, there have been a limited number of studies that have examined the effect of assisted hatching (AH) on live birth rate (LBR). As a result, there is insufficient evidence that AH improves birth rates (Level C).

There is good evidence that AH slightly improves clinical pregnancy rates (CPR) in poor prognosis patients, including those with prior failed in vitro fertilization (IVF) cycles and who have a poor prognosis (Level A).

AH appears to be associated with an increased risk of multiple pregnancy (Level A), but there is insufficient evidence that it is associated with an increased risk of monozygotic (MZ) twin pregnancy (Level C).

Until data about LBR are available and in the context of increased risk of multiple pregnancy, it is premature to recommend AH in all patients with poor prognosis.

Recommendation

AH should not be recommended routinely for all patients undergoing IVF (Level C).

Definitions

Level of Evidence

Level I: Evidence obtained from at least one properly designed randomized, controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

Level III: Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Strength of Recommendations

Level A: There is good evidence to support the recommendations, either for or against.

Level B: There is fair evidence to support the recommendations, either for or against.

Level C: There is insufficient evidence to support the recommendations, either for or against.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Infertility

Guideline Category

Technology Assessment

Treatment

Clinical Specialty

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the role of assisted hatching in in vitro fertilization (IVF)

Target Population

Women undergoing in vitro fertilization (IVF)

Interventions and Practices Considered

In vitro fertilization (IVF) using assisted hatching (*not recommended routinely*)

Major Outcomes Considered

- Clinical pregnancy rates (CPR)
- Live birth rates (LBR)
- Implantation rate
- Monozygotic (MZ) twin pregnancy rate

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic literature search was performed using the following two search strategies:

(Assisted OR zona hatching OR drilling OR thinning) AND (pregnancy OR implantation OR live birth)
AND blastocyst
Assisted hatching AND in vitro fertilization (IVF) (Humans [Mesh] AND English [lang])

The literature search was performed from 1966 through November 2013. Studies were eligible if they met one the following criteria: primary evidence (clinical trials) which assessed the effectiveness of procedure correlated with an outcome measure (pregnancy, implantation or live birth rates), meta-analyses, and relevant articles from bibliographies of identified articles.

Randomized trials, cohort studies, case control studies and cross-sectional studies written in English were selected for review. Two reviewers screened the papers by title and abstracts. Then full text papers were obtained and reviewed.

Number of Source Documents

A total of 312 articles were identified, of which 68 were included as relevant.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Level I: Evidence obtained from at least one properly designed randomized, controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

Level III: Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data were extracted using a standardized form including the following information: author and year of publication, study design, types of participants, sample size, outcomes measured, and study results citing odds ratio (OR) and relative risk (RR) if available.

Quality of the studies was assessed by reviewing the study design, assessment of exposure and outcome, confounders, bias, statistical methods, and reported limitations. The quality of the evidence was evaluated using grading system found in the "Rating Scheme for the Strength of the Evidence" field. The strength of the evidence was evaluated by the guideline committee after reviewing the results of the literature search and recommendations were graded as described in the "Rating Scheme for the Strength of the Recommendations" field.

Methods Used to Formulate the Recommendations

Not stated

Description of Methods Used to Formulate the Recommendations

Not applicable

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Level A: There is good evidence to support the recommendations, either for or against.

Level B: There is fair evidence to support the recommendations, either for or against.

Level C: There is insufficient evidence to support the recommendations, either for or against.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This document was reviewed by American Society for Reproductive Medicine (ASRM) members, and their input was considered in the preparation of the final document. The Practice Committee and the Board of Directors of the ASRM and the Society for Assisted Reproductive Technology (SART) have approved this report.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Many assisted reproductive technology (ART) programs have incorporated the use of assisted hatching (AH) in an effort to improve clinical outcomes. There is good evidence that AH slightly improves clinical pregnancy rates in poor prognosis patients, including those with prior failed in vitro fertilization cycles and who have a poor prognosis.

Potential Harms

- The assisted hatching procedure may be associated with specific complications independent of the in vitro fertilization (IVF) procedure itself, including lethal damage to the embryo and damage to individual blastomeres with reduction of embryo viability. In addition, artificial manipulation of the zona pellucida (ZP) has been associated with an increased risk of monozygotic (MZ) twin pregnancy.
- Despite limited evidence of the benefits or risks, patients whose embryos undergo assisted hatching are often treated with antibiotics and steroids before and after embryo transfer (ET), exposing them to the potential risks and side effects of such treatments.

Qualifying Statements

Qualifying Statements

This report was developed under the direction of the Practice Committee of the American Society for

Reproductive Medicine (ASRM) in collaboration with the Society for Assisted Reproductive Technology (SART) as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Patient Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology. Role of assisted hatching in inÂ vitro fertilization: a guideline. Fertil Steril. 2014 Aug;102(2):348-51. [19 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Aug

Guideline Developer(s)

American Society for Reproductive Medicine - Nonprofit Organization

Source(s) of Funding

American Society for Reproductive Medicine

Guideline Committee

Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology

Composition of Group That Authored the Guideline

Committee Members: Samantha Pfeifer, MD; Roger Lobo, MD; Rebecca Sokol, MD; Jeffrey Goldberg, MD; Gregory Fossum, MD; Michael Thomas, MD; Margareta Pisarska, MD; Eric Widra, MD; Mark Licht, MD; Jay Sandlow, MD; John Collins, MD; Marcelle Cedars, MD; Mitchell Rosen, MD; Michael Vernon, PhD, HCLD; Owen Davis, MD; William Catherino, MD, PhD; Dan Dumesic, MD; Randall Odem, MD; Clarisa Gracia, MD, MSCE; Kim Thornton, MD; Samantha Butts, MD, MSCE; Robert Rebar, MD; Richard Reindollar, MD; Andrew La Barbera, PhD

Financial Disclosures/Conflicts of Interest

All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [American Society for Reproductive Medicine Web site](#) .

Availability of Companion Documents

Continuing medical education (CME) credit related to this guideline is available from the [American Society for Reproductive Medicine Web site](#) .

Patient Resources

The following is available:

Assisted hatching. Fact sheet. Birmingham (AL): American Society for Reproductive Medicine; 2015. 1 p. Available from the [ReproductiveFacts Web site](#) . Also available in Spanish from the [ReproductiveFacts Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on March 27, 2017. The information was verified by the guideline developer on April 17, 2017.

This NEATS assessment was completed by ECRI Institute on June 22, 2017. The information was verified by the guideline developer on July 25, 2017.

Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouse® (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the [NGC Inclusion Criteria](#).

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.